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March 28, 2013

Via ECF and First Class Mail

The Honorable Michael A. Shipp
United States District Court
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street, Room 2020
Trenton, NJ 08608

Re: Stephen Trewin, *et al.* v. Church & Dwight, Inc.
Civil Action No: 3:12-cv-01475 (MAS)(DEA)

Dear Judge Shipp:

We are counsel for Plaintiffs in the above-captioned matter. We wish to bring to the Court's attention the opinions issued in two separate cases pending in the United States District Court for the District of New Hampshire, where each court denied a defendant's motion to dismiss, based on the argument that the allegations regarding triclosan warranted dismissal of the complaints under the primary jurisdiction doctrine. Copies of the opinions in *In re: Colgate-Palmolive Softsoap Antibacterial Hand Soap Marketing and Sales Practices Litigation*, No. 12-md-2320-PB (D.N.H., March 18, 2013) ("*Colgate*") and *In re: Dial Complete Marketing and Sales Practices Litigation*, No. 11-md-2263-SM (D.N.H., March 26, 2013) ("*Dial Complete*") are enclosed for the Court's reference.

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In both cases, plaintiffs raised, *inter alia*, consumer fraud claims based on allegations that the marketing and labeling of the antibacterial soap products at issue, both of which contained triclosan, were false and misleading. While the opinions are obviously non-binding, the facts in those cases and arguments made by those defendants are directly relevant to Church & Dwight's argument here, that this Court should defer any ruling regarding triclosan (one of the ingredients in the deodorant at issue) to the FDA under the primary jurisdiction doctrine. *See e.g.*, Defendant's Reply Memorandum (Docket Item No. 50) at 11 ("the safety of triclosan, if it is an issue in this case, should not be litigated by this Court.").

In *Colgate*, defendant argued that the FDA had been studying the safety, efficacy, testing and labeling of products containing triclosan and that proposed regulations were "imminent" so that the court should invoke the primary jurisdiction doctrine, dismiss plaintiffs' claims, and refer the case to the FDA for an administrative determination. Church & Dwight raises similar arguments here. The *Colgate* court rejected this position, holding:

[P]laintiffs seek to prove that Colgate made implied claims that Softsoap Antibacterial is superior to other products; that it misrepresented Softsoap Antibacterial's effectiveness; and that it misled consumers with unsubstantiated claims about its products. To resolve those claims, the court will examine the state of scientific knowledge in the past, when Colgate made its advertising and labeling claims relating to Softsoap Antibacterial's safety and effectiveness. It will determine what data Colgate possessed to support its marketing claims at the time they were made and whether Colgate ignored data that contradicted its claims. The court will also determine Colgate's marketing campaign for Softsoap Antibacterial. Essentially, this litigation is backward-looking; it seeks to determine whether past conduct was misleading.

The FDA's monograph process, in contrast, is forward-looking. It will determine the permissible content of future product labels. It will establish the permissible concentrations of triclosan in consumer hand soaps, if it permits use of the ingredient at all. The monograph will articulate the FDA's findings, based on the

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current state of scientific knowledge, about the safety and effectiveness of triclosan as used in consumer hand soaps.

The FDA will not draw any factual conclusions about Colgate's past conduct. The agency will not address whether Colgate's past advertising claims were substantiated. Nor will the FDA's monograph shed light on what information Colgate knew or could have known at the time it made the advertising and labeling claims at issue in this case. The FDA will not address whether Colgate's past product labels or advertising claims were misleading when they were made or make any pronouncement on how a reasonable consumer would interpret Colgate's marketing claims. Accordingly, although the FDA's conclusions may touch on some issues in this case, the case does not turn on factual disputes that lie at the heart of the FDA's regulatory authority.

Colgate decision at 18-20.

The court also found that "since both federal courts and the FTC are competent to decide whether labeling and advertising statements were false or misleading, the FDA's special expertise is not required to resolve these issues." *Id.* at 23. In addition, the *Colgate* court held that a decision by the FDA would not materially aid the court in resolving plaintiffs' false advertising claims. *Id.* Finally, the court held that "any minimal value that an FDA ruling might have on the resolution of this case is greatly outweighed by the harm that the plaintiffs will suffer if the action is delayed, potentially for several years, until the FDA makes a determination concerning the effectiveness of hand soaps containing triclosan." *Id.* at 24.¹

For the same reasons, as well as all of the reasons set forth in Plaintiffs' Opposition To Defendant Church & Dwight, Inc.'s Motion To Dismiss Plaintiffs' Amended Complaint, this Court should deny Defendant's Motion to Dismiss in this case to the extent it is based on the primary jurisdiction doctrine.

¹ The *Dial* court reached the same conclusions, relying on the *Colgate* decision. *See Dial*, slip op. at 13-17.

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We will be prepared to discuss this development and the implications on the pending matter at any oral argument in this case.

Respectfully submitted,

s/James C. Shah

James C. Shah

JCS/sm

Enclosures

cc: Counsel of Record (Via CM/ECF)